UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

STEVEN BRUCE,

Plaintiff,

v.

ALEX M. AZAR,

Defendant.

Case No. 18-cv-05022-HSG

ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

Re: Dkt. Nos. 90, 94

United States District Court
Northern District of California

Pending before the Court are the parties' cross motions for summary judgment. Dkt. Nos. 90 ("Pl. Mot"), 94 ("Def. Mot"). The Court held a hearing on the motions on December 5, 2019. After carefully considering the papers and the parties' arguments, the Court **DENIES** Plaintiff's motion for summary judgment and **GRANTS** Defendant's motion for summary judgment.

I. BACKGROUND

Plaintiff Stephen Bruce filed this action on August 16, 2018, seeking judicial review of the final decision by the Medicare Appeals Council ("MAC") denying Plaintiff coverage for the drug Serostim. Dkt. No. 1. The Court provides the relevant statutory framework and facts below.

A. Part D of the Medicare Act

The Medicare Act, established under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, provides coverage for certain medical services to eligible aged and disabled individuals. *Maximum Comfort Inc. v. Sec'y of Health & Human Servs.*, 512 F.3d 1081, 1083 (9th Cir. 2007). At issue here is Part D of the program, which is a voluntary prescription drug benefit program established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Modernization Act"). Pub. L. No. 108–173, 117 Stat. 2066 (2012). Part D provides coverage for certain types of drugs: (1) prescription drugs; (2) biological products;

(3) insulin and insulin supplies used to inject insulin; and (4) vaccines. *See* 42 U.S.C. § 1395w-102(e).

Under the statute, the term "covered part D drug" includes "any use of a covered part D drug for a medically accepted indication." *Id*. § 1395w-102(e)(1). The definition of "medically accepted indication" depends on whether the medication is used in an "anticancer chemotherapeutic regimen." *Id*. § 1395w-102(e)(4). If not, as is the case here, "medically accepted indication" is defined by cross-reference to 42 U.S.C. § 1396r-8(k)(6), which states:

> The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

Id. § 1396r-8(k)(6). The "compendia described in subsection (g)(1)(B)(i)" consist of: (1) the American Hospital Formulary Service Drug Information ("AHFS-DI"); (2) United States Pharmacopeia-Drug Information ("USPDI") (or its successor publication); and (3) the DRUGDEX Information System. *Id*. § 1396r-8(g)(1)(B)(i).

B. Plaintiff's Requests for Coverage of Serostim

Plaintiff is a Medicare beneficiary enrolled in Part D, administered by Envision in 2016 and Blue Shield in 2017. AR 49, 720.[1] In July 2016, he was diagnosed with lipodystrophy or wasting syndrome (used interchangeably in Plaintiff's case), a rare disorder which causes Plaintiff to suffer from severe and progressive weight loss. AR 82. To halt this weight loss, his primary physician, Dr. Louis J. Cubba, M.D., prescribed Serostim, which Dr. Cubba said was the only medication "that was able to successfully halt his progressive, life threatening, weight loss." *Id*.

Plaintiff submitted a request for coverage of Serostim to his insurers, Envision in 2016 and Blue Shield in 2017. *See* AR 184–85, 192–94, 630–31. Both insurers denied coverage because Plaintiff's use of Serostim for lipodystrophy was not prescribed for a "medically accepted indication." *See id*.

[1] References to AR refer to the certified administrative record filed and attached as exhibits to the Declaration of Kimberly A. Robinson. Dkt. Nos. 64-7, 64-8, 64-9, 64-10.

i. Plaintiff's Appeal in 2016

In September 2016, Plaintiff filed a reconsideration request with the independent review entity ("IRE"). AR 1217–18. The physician reviewer found that the "Part D Plan was correct in denying the request for Serostim," because it was prescribed for "off-label (non-FDA) approved uses," and the Medicare-approved compendia "do not contain any citations to support the use of this drug for these conditions." AR 1217.

Plaintiff requested a hearing before an administrative law judge ("ALJ"). AR 997. ALJ James Myles held a telephone hearing with Plaintiff on October 21, 2016, and on November 15, 2016, ALJ Myles issued a decision against Plaintiff. AR 997–1003. ALJ Myles stated that while he was "sympathetic to Mr. Bruce's situation," he was bound by Medicare Part D coverage requirements, which state that the "proposed used of Medication must be supported by approved on label use by the FDA or Medicare-recognized compendia." AR 1002. Based on the record and evidence presented, ALJ Myles found that Plaintiff was requesting coverage of Serostim for "off-label, non-FDA approved uses which are not 'medically accepted indications' as defined by Medicare law." AR 1002–03. Therefore, he concluded that Plaintiff's Plan was not required to provide coverage for Serostim. AR 1003.

Plaintiff appealed ALJ Myles's decision to the MAC. AR 1031–32. The MAC remanded the case back to ALJ Myles, because the claim file did not include a copy of "either the FDA label or the Medicare-approved compendia." AR 1032. The MAC instructed the ALJ to obtain a copy of the Plan's "Evidence of Coverage and formulary for 2016, the FDA label, and the Medicare-approved compendia." *Id.*

On remand, ALJ Myles issued another unfavorable decision on March 30, 2018. AR 720–27. He did not dispute Plaintiff's credibility, or that Serostim is helpful for Plaintiff to maintain his weight. AR 726–27. However, he concluded that "[g]iven the information found on the FDA's label and the Medicare approved compendia, Serostim is not prescribed for a medically accepted indication." AR 727. Plaintiff again appealed the decision. *See* AR 12.

ii. Plaintiff's Appeal in 2017

After Blue Shield denied coverage in 2017, Plaintiff filed a reconsideration request with

the IRE. *See* AR 619. The IRE, after conducting a "new and independent review of the appeal," concluded that Plaintiff's Part D Plan was not required to cover Serostim. *Id*. The physician reviewer determined that there "are no citations in the Medicare approved compendia that support the use of Serostim for the diagnosed condition," and as a result, "the drug is not being prescribed for a medically accepted indication as defined by Medicare law." AR 620.

Plaintiff then requested an ALJ hearing on May 1, 2017. AR 660. ALJ Jeffrey Gulin dismissed the request because he found that ALJ Myles's decision was based "on the same facts and on the same issues" as the appeal before him and thus binding. *Id*. The MAC remanded the case back to ALJ Gulin, because it found that the facts in the decision by ALJ Myles were "not the same as the facts at issue here," given Plaintiff was seeking coverage under two different Medicare Part D prescription drug plans (in other words, under Envision in 2016 and Blue Shield in 2017). AR 323. After a telephone hearing, ALJ Gulin issued an unfavorable decision on March 15, 2018. AR 49–56. Based on the evidence and record presented, he found that Serostim was not being used for a medically accepted indication. AR 56. Plaintiff appealed the decision. *See* AR 12–17.

iii. MAC Decision

The MAC reviewed and adopted both ALJs' decisions. *Id*. In its July 12, 2018 order, the MAC acknowledged Plaintiff's argument "that there is no realistic difference between the Human Immunodeficiency Virus and the virus which the appellant asserts has caused the autoimmune disease that is the basis for his condition." AR 16. However, the MAC found that "the similarity of a diagnosis to a covered diagnosis is simply not a basis on which we direct Part D coverage." *Id*. Because the FDA label and Medicare compendia did not list Plaintiff's prescribed use, the MAC concluded that Part D did not cover Serostim in Plaintiff's case.[2] *Id*.

C. This Action

Following the MAC's decision, Plaintiff filed this civil action challenging the July 2018

[2] Plaintiff also sent a letter to the Administrative Appeals Judge, requesting that the MAC "make findings on the Section 504 of the Rehabilitation Act of 1973, the due process clause of the Fifth Amendment, and offer a reason for why [the MAC] remanded these cases without including the above copy of the 'FDA label or the AHFS-DI' for Serostim." AR 8–9. The MAC construed the letter as a request to reopen its July 2018 decision and held that Plaintiff did not show good cause for reopening. AR 2.

MAC decision. Dkt. No. 1. He named Blue Shield, Envision, and Alex M. Azar II, Secretary of the United States Department of Health and Human Services ("DHHS"), as Defendants. *Id.* Defendants filed motions to dismiss, which the Court granted on June 18, 2019. Dkt. No. 83. Currently, the only remaining Defendant is DHHS, and the only remaining cause of action is Plaintiff's first cause of action, which seeks review of the final decision by the MAC.[3] *See id.*

II. STANDARD OF REVIEW

A Medicare beneficiary may obtain judicial review of the MAC's final decision denying Part D coverage under 42 U.S.C. § 405(g). *See* 42 U.S.C. § 1395w-104(h) (incorporating Part C's judicial review provision, § 1395w–22(g), which provides for judicial review under § 405(g)). The governing regulations specify that a Part D beneficiary may obtain court review if the amount in controversy meets the threshold requirement estimated annually by the Secretary of DHHS. 42 C.F.R. § 423.2136(a).

Under the Administrative Procedure Act, the district court may set aside an agency decision that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Palomar Med. Ctr. v. Sebelius*, 693 F.3d 1151, 1159 (9th Cir. 2012) (citation and quotations omitted). A district court may disturb the decision to deny benefits only if the decision is either not supported by substantial evidence, or is based on legal error. *Burch v. Barnhart*, 400 F.3d 676, 679 (9th Cir. 2005). "Substantial evidence means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. The evidence must be more than a mere scintilla, but may be less than a preponderance." *Molina v. Astrue*, 674 F.3d 1104, 1110–11 (9th Cir. 2012) (quotations and citations omitted). The court must consider the administrative record as a whole, weighing both the evidence that supports the decision and the evidence that detracts from it. *McAllister v. Sullivan*, 888 F.2d 599, 602 (9th Cir. 1989). If the evidence can rationally

[3] The Court dismissed Plaintiff's second and third causes of action, which alleged that Defendants violated Plaintiff's due process rights and Section 504 of the Rehabilitation Act of 1973, because the Court determined that it did not have subject matter jurisdiction over those two claims under *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1 (2000). Dkt. No. 83 at 5–8. Plaintiff attempts to relitigate those issues in his motion for summary judgment. Pl. Mot. at 13–15. But the Court declines to do so, and will not consider Plaintiff's arguments as to those two causes of action.

be interpreted in more than one way, the court must uphold the agency's decision. *Mayes v. Massanari*, 276 F.3d 453, 459 (9th Cir. 2001).

III. DISCUSSION

A. Plaintiff's Prescription for Serostim Is Not For a "Medically Accepted Indication"

As already discussed, Plaintiff's use of Serostim is covered by Part D only if it is used for a "medically accepted indication," meaning it is prescribed for an FDA-approved use or listed in one of the approved compendia. *See* 42 U.S.C. § 1396r-8(k)(6). Upon review of the record presented, the Court finds that Serostim was not used for a medically accepted indication.

The FDA label included in the record states that Serostim is "indicated for the treatment of HIV patients with wasting or cachexia to increase lean body weight, and improve physical endurance." AR 317; *see also* AR 16 (MAC decision citing to the FDA website and finding the same). Plaintiff does not dispute this, nor does he dispute that he does not have HIV-related wasting syndrome. As to the compendia requirement, the DRUGDEX compendium included in the administrative record lists the following uses for Serostim: cachexia associated with AIDs, growth hormone deficiency, and short bowel syndrome. AR 787–88. It also lists fat maldistribution for HIV infection as a non-FDA (or off-label) use. AR 788. ALJ Gulin noted that the AHFS-DI compendium did not identify any uses for Serostim outside the FDA approved indications.[4] AR 25. Based on the administrative record, there is no suggestion that any of the relevant compendia list non-HIV-related lipodystrophy as a use for Serostim.

Plaintiff argues that the phrase "medically accepted indication" is merely "illustrative, not definitional." Dkt. No. 98 at 5. But as DHHS notes, district courts in this circuit have rejected

[4] Plaintiff, in his reply brief, again seeks to supplement or complete the administrative record, a request the Court previously denied. Dkt. No. 98 at 6. He also filed two administrative motions requesting to file extra-record evidence. Dkt. Nos. 100, 102. The Court incorporates its prior analysis finding that Plaintiff failed to rebut with clear evidence the presumption that the record is complete, or present any evidence that an exception applies to allow the Court to consider extra-record evidence. *See* Dkt. No. 83 at 10–11. Accordingly, the Court **DENIES** Plaintiff's administrative motions to file additional documents. *See* Dkt. Nos. 100, 102. And even were the Court to consider the additional materials Plaintiff seeks to introduce, the Court finds that these materials would not change its analysis.

that very same argument. *See, e.g.*, *Nievod v. Sebellius*, No. C 11-4134 SBA, 2013 WL 503089, at *10 (N.D. Cal. Feb. 8, 2013); *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1047 (C.D. Cal. 2016) ("We note, however, that CMS and a clear majority of district courts have read this clause to incorporate the medical acceptance limitation, while only one district court has read it differently." (collecting cases)); *Broome v. Burwell*, No. 6:14-CV-01248-MC, 2015 WL 1526532, at *4 (D. Or. Apr. 1, 2015); *Rickhoff v. U.S. Sec'y ex rel. Dep't of Health & Human Servs.*, No. CV-11-2189-PHX-DGC, 2012 WL 6177411, at *4 (D. Ariz. Dec. 11, 2012). The Court agrees with the reasoning of these decisions, and finds it clear under the plain terms of the statute that a covered Part D drug must satisfy the medically accepted indication requirement.[5]

According to Plaintiff, providing coverage only to those who have HIV-related lipodystrophy, and not to those who have non-HIV-related lipodystrophy, is "unreasonable based on the lack of [a] relevant connection." Pl. Mot. at 12; *see also* Dkt. No. 98 at 8 (arguing it is "irrational and violative of substantive due process" to require Plaintiff to have HIV with lipodystrophy to qualify for coverage). Whether Part D *should* cover Plaintiff's use of Serostim to treat his condition because it has similar symptoms to those of patients with covered conditions is a policy matter not within the Court's competence to decide. The Court echoes the sentiments expressed by the MAC and ALJs, and is sympathetic to Plaintiff's situation. But the only issue before the Court is whether the MAC's decision to deny coverage either was not supported by substantial evidence or constituted legal error. Based on the record and for the reasons already discussed, the Court finds the MAC's decision to be supported by substantial evidence and not based on legal error.

B. 42 C.F.R. § 423.578 Exception

Plaintiff also argues that the MAC failed to apply an exception under 42 C.F.R. § 423.578.[6] Pl. Mot. at 14. Contrary to Plaintiff's argument, the MAC did consider this exception and held that Plaintiff did not qualify. AR 6. To qualify for a formulary exception under 42

[5] The Court finds Plaintiff's out-of-circuit cases inapposite or not persuasive. *See* Dkt. No. 98 at 5, 9 (citing cases).

[6] Plaintiff appears to invoke 42 C.F.R. § 421.2112(a) as another exception, Pl. Mot. at 14, but this regulation outlines the requirements for requesting review of an ALJ action.

C.F.R. § 423.578(b), the drug must be "medically necessary, consistent with the physician's or other prescriber's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug." 42 C.F.R. § 423.578(b). However, "[n]othing in this section may be construed to allow an enrollee to use the exceptions process set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug." *Id.* § 423.578(e).

The MAC found that the "formulary process cannot be used to cover a drug that does not meet the definition of a Part D drug." AR 6. Because Serostim in Plaintiff's case "does not meet the definition of a Part D drug," the MAC concluded that "there is no basis on which a formulary exception for Serostim can be granted." *Id.* As already discussed, Plaintiff has not shown that his prescribed use of Serostim meets the definition of a Part D drug. Thus, the Court does not find the MAC's determination to be arbitrary, capricious, or not in accordance with the law.

IV. DISCUSSION

The Court **DENIES** Plaintiff's motion for summary judgment, **GRANTS** Defendant's motion for summary judgment, and **DENIES** Plaintiff's administrative motions to file additional documents. Dkt. Nos. 90, 94, 100, 102. The MAC's decision is affirmed. The Court directs the Clerk to enter judgment in Defendant's favor and close the case. No further filings will be accepted in this closed case.

IT IS SO ORDERED.

Dated: 12/16/2019

HAYWOOD S. GILLIAM, JR.
United States District Judge